Market, regulation, market, regulation

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Abstract: This paper focuses on the European Regulatory system which was settled both for opening the Single Market for products and ensuring the consumers' safety. It claims that the New Approach and Standardization, and the Global Approach to conformity assessment, which suppressed the last technical barriers to trade in Europe, realized the free movement of products by organizing progressively several orders of markets and regulation. Based on historical and institutional documents, on technical publications, and on interviews, this article relates how the European Commission and the Member States had alternatively recourse to markets and to regulations, at the three main levels of the New Approach Directives implementation. The article focuses also more specifically on the Medical Devices sector, not only because this New Approach sector has long been controversial in Europe, and has recently been concerned by an important regulatory failure, but also because it is regulated by totally other means in the United States of America. At a time when the Medical Devices sector is part of TTIP discussions, this article allows a better understanding of the diverse stakeholders and regulators positions in the EU.

1. Introduction

The CE-sign has become common in Europe and other parts of the world and amounts to an emblem of the successful making of the Single Market. As a sign of conformity with relevant EU regulation it both points to and veils the often complex processes and levels of regulation and markets tied together in order to make a reality the visions of the free movement of products. A product which carries the sign has a passport that allows it, at least in principle, to move unhindered across member state boundaries in the EU, and thus the success of the Single Market for products in many ways hinges on the crystallization of regulation, technical standards, certification and accreditation into granting – or not granting – a product the right to carry this 'passport'. But the success of the Single Market is not without limits and cases such as the recent breast implant case bear witness to this. In this case products carrying the CE-sign and thus indicating to fulfil requirements of the Medical Devices Directive resulted in sincere harm to those who had it implanted. This case may be a mere accident. But there are also findings that suggest that it is an indication of tensions internal to the system build to backup the CE-sign, or even an indication of a malfunction of the system. As such it invites to a scrutiny of the Single Market for products.

Often markets and regulation are discussed as two areas delineated by a relative specific division of work (Block & Evans 2005). Markets are thus expected to deliver allocation of goods as a result of competition while regulation – typically issued by states – is about formulating and enforcing requirements, i.e. the quintessential political function of collectively binding decisions. But in reality markets and regulation are often teased together in ways less clear cut such as when regulation uses markets to make other markets. In the Single Market this has become the case in so far as the free movement of products is achieved by making a market for harmonized standards, which again is brought to bear through a market for certification services. It is these orders of markets and regulation that a case such as the breast implant case should be seen in the light of and that it can help us understand better.

This paper claims that the Single Market builds on orders of markets and regulation marked by an internal contradiction as requirements to products need to be general and open to interpretation. Without a considerable degree of such openness the system would remove the discretion required for independent bodies to make decisions on standards, certification and accreditation. But the same openness also make normal (Perrow 1984) that regulation does not work as intended, sometimes with harmful consequences as in the breast implant case. We use the notion of *orders*, understood as the application of a specific type of operation on operations of the same type, to add notions of first, second and third order markets to the literature on technical standardization, economic sociology and political science as a way to develop a better understanding of the Single Market and other market-making projects as well (section 2: Review). Based on document studies and interviews (section 3: Methods) we undertake first a historical analysis of how these levels have been established in the making of free movement of products in EU (section 4) and then we analyze the specific case of breast implants and the Medical Devices Directive (section 5). In the following discussion (section 6) we relate our analysis of orders to the literature and to the on-going talks on TTIP. Section 7 concludes the paper.

2. Review

Scholars who work on standards have generally paid much more attention to the "standard setting" phase than to the implementation phases of standards. However, a few scholars try and have a more systemic approach of standardization processes, by including in their investigations the certification and accreditation ("certification of the certifiers") processes (Loconto & Busch, 2010) through which standards are implemented. This article, which is focused on the specific case of the European New Approach for standardization, lie within the scope of this recent way of examining standardization. In regards to the New Approach, it has been observed that there is a precarious relation between relatively broad framework directives and the concretization of the general requirements in the form of technical standardization (Frankel & Højbjerg 2007). Observers point out that the general requirements of New Approach directives can hardly stand alone: the generality also implies that they can be interpreted differently and as a consequence have quite different practical implications. What this implies is that harmonized standards contribute to understanding the general requirements.

Standardization, certification and accreditation are by no means unknown to the literature on technical standardization (e.g. Egan 2001); yet it is generally not systematically linked to market making (Boström & Garsten 2008). This is an important issue to tackle because it can help us develop a better understanding of the relation of regulation and markets. This theme is a standing interest of economic sociology. While it sometimes in popular parlour is presented as if markets and political regulation are opposed or at least conflicting, as reflected in calls for 'less state – more market' (or vice versa), there is a widespread agreement in economic sociology that political regulation is important for the making of markets. Karl Polanyi (1957), to take a central and classic example, argues that 'free markets' do not emerge by themselves but are instituted by political intervention that 'disembeds' economic relations from their local, social relations. In similar ways Neil Fligstein (1986, 2001, 2008) argues that markets are politically constructed as they require regulation of property rights, rules of exchange and governance structures, to all of which political regulation is central. This view of markets as politically constituted (at least for central parts) finds a wide tenor in the field of

economic sociology (Block 1994). Moreover, a similar argument is found in neo-liberal thought (Mirowski 2013), in Foucault-inspired studies of markets and market ideology (Foucault 2008; Davies 2013) and in sociology of economic thought (Gane 2013).

There are, however, also disagreements and a central tenor in recent developments in economic sociology (broadly speaking) argues that privileging political regulation draws attention away from material conditions of markets, such as the specific devices used to produce, disperse and process information (such as cables, formulas, spreadsheets and algorithms) (MacKenzie et al. 2012). While this approach highlights important parts of market-making, it does also tend to analyze markets as tangled and complex networks or assemblages, and here it is helpful to move focus to concepts that allow better for a reduction of the complexity of the data gathered. The notion of orders is useful for doing this. The notion of orders allow for analyzing markets as well as regulation and other social regularities without being bound by institutional structures. An analysis that focuses on orders, understood as the application of a specific type of operation on operations of the same type, by contrast allows us to analyze market orders across diverse institutional fields, not unlike what is suggested by the new economic sociology but at the same time have tools to summarize architecture and internal tensions by help of such notions as first, second and third order markets.

3. Methods

This study builds on historical documents, primarily from EU institutions, such as Commission green papers, white papers and annual reports, hearings from amongst others the ESC, reports from debates of the European Parliament and guides and information on the Single Market. Also publications of national and European technical standardization organizations are consulted as well as agreements, and mutual understandings of the EU with European technical standardization organizations have been consulted. As a supplement background interviews have been conducted with national civil servants and actors in technical standardization.

The Medical Devices sector, which is regulated in Europe through three Directives (Active implantable medical devices, 1990; Medical devices, 1993; In vitro diagnostic medical devices, 1998), certainly is the most publicly debated New Approach sector: as political and technical decisions concerning medical devices regulation have long been controversial (Altenstetter, 2008), we could lean on a great number of documents and on a few academic analysis. Otherwise, we took part in a recent academic conference (2013), the theme of which was the (on-going) revision of the Medical devices (European) regulation, and analysed a recent regulatory failure and its judgments by French courts.

4. Historical background: market and regulation as unfolded in the Single Market for products

Although a complex undertaking, the Single Market as conceived of in the Treaty of Rome (1958) was nowhere as complex an undertaking as it became later in time. The guiding idea was that the member states let their territorial boundaries work as market barriers also. Barriers were an act of will and could thus also be removed, without essentially affecting the inner working of each member state: without barriers a market common to the member states would emerge. The barriers in focus were tariffs and customs as well as of the so-called *measures*

with equivalent effect. Common to these barriers was, that they all were conceived of as discrimination of foreign products, thus giving home-market products advantages. Tariffs and customs were removed faster than the plan entailed in the Treaty. National approval and testing procedures were scrutinized for being *measures with equivalent effect as customs*, and were in many cases found to be discriminatory. During the 1960s the definition of barriers to trade was widened as it also came to include non-discriminatory measures. Conceptually this change was debated intensively by the Commission, the European Parliament and others, and a central issue was how member state measures could work as barriers if they were non-discriminatory?

The outcome was that barriers sometimes originate in the difference between member states. When regulation of a specific product in one member state differs from that of other member states, there is likely to be a barrier even if the regulation does not discriminate between imported and home-market products. Such barriers have become known as *technical barriers to trade*. This more encompassing definition of barriers implied a multiplication of the number of barriers to be removed: every single regulation of the member states potentially constituted a barrier. But not only were there more barriers to remove, they were also often more cumbersome to remove. The reason for this was that member state regulation was to be *harmonized*. This implied that the EU was to adopt regulation for tractor seats and several other product areas and in this way, step by step, remove barriers stemming from differences between member state regulation. While the removal of tariffs and customs had taken place ahead of the plan, technical barriers to trade appeared as an endless undertaking; not only was it difficult to formulate a proposal for a harmonization but in several cases the adoption was underway for years with the result that the Commission withdrew the proposal as it was considered outdated. One crucial reason for this slow pace was certainly that the inner working of each member state was affected. And the market was not simply expected to emerge when barriers were removed. By contrast the common market was also seen as requiring detailed regulation to become a reality.

On this backdrop the so-called New Approach (adopted in 1985) was ground-breaking. A 'division of work' between regulation and technical standardization was agreed upon: the EU was to adopt framework directives, setting the essential requirements to a specified category of products and these essential requirements were to remain relatively untouched by innovation and the technical developments of the regulated products. On the other hand the European technical standardization organizations were to develop technical standards that concretized the essential requirements and offered producers one possible way to comply with the essential requirements. The significance of the New Approach is not primarily the around 30 New Approach directives that have since been adopted but more the vast amount of regulation that the EU need not adopt; the broad scope of New Approach directives simply cover areas that in the 'old approach' were typically regulated by numerous regulations. New Approach directives are 'implemented' in two ways: on one hand they are to be transposed into the regulation of the member states. On the other hand technical standards are to be approved as congruent with the general requirements of the respective directive and thus becoming so-called 'harmonized standards'.

When the New Approach was adopted, hardly any European standards and *mandating procedures* were set up, that is procedures by which the Commission agreed with and funded the European Standardization Organizations to deliver work in a specific area. Over time a mar-

ket for technical – and harmonized – standards has developed: these standards are not freely available, as regulation normally is, but are themselves products protected by intellectual property rights and can be bought at the market. The market for New Approach standards is in ways oligopolistic as the dominating supplier is the European Standardization Organizations;[1] in this respect the national standardization organizations compete to sell the same product (they are not cartels).

The CE-sign – the 'passport' the paper opened with – indicates that the specific product on which it is placed is congruent with the essential requirements of the relevant New Approach directive. It is safe to assume that in most cases this is achieved by applying harmonized standards. "Harmonized European Standards" should be set up by ESO, and would presumably be equivalent to essential requirements, but allow easier conformity assessments procedures. Most of the time, producers are responsible of conformity assessments procedures, but in a few cases (high risk sectors or products), producers have to call, with regards to these procedures, for independent third-party bodies' services. In the New Approach framework, these public or private bodies are first appointed by their domestic Member State, and notified by each Member State to the Commission and to the other Member States (which may refuse or contest a proposed body). Then, the sector Directive "Notified Bodies" list is promulgated by the Commission, so that every producer may call for any of them, with regard to conformity assessments procedures. So, inside a given industrial sector, European Notified Bodies are both regulating industrial markets and their risks in Europe, and competing with each other inside certification markets (Galland, 2013). Thus a market for certification has in the EU been established over the years as a way to make a Single Market for products. As opposed to the territorial delimitation of public authority, these market-based bodies compete on a EU-wide market.

General conformity assessments procedures are detailed in the Global Approach to conformity assessment Council resolution (1989) and more precisely in a 1993 Council Decision[2]. The Global Approach describes the diverse "modules" (type product trial, methods for assessing conformity with type product, standards for assessing quality management system, …) which may be used or should be combined for guaranteeing that essential safety requirements are fulfilled. It is worth to be noticed at this stage that producers and notified bodies keep some room to manoeuvre, which may be different from one sector Directive to another one, when choosing the "modules" they will use for assessing conformity of products with the essential safety requirements.

Thanks to the Global Approach framework, and because the number of New Approach Directives had been growing since 1988, the Notified Bodies' population grew simultaneously, all the more because of the successive Europe enlargements (1986, 1995, 2007). But the solution of market(s) creation of competing Notified Bodies, one market by Directive or sector, appeared soon as an incomplete way for regulating the CE marking procedures. The New and the Global Approaches stipulate that not only Notified Bodies are first appointed by their re-

[1] If one considers not primarily New Approach standards but standars more generally then ESO would not be in position of oligopoly, but that would also imply that the focus is not primarily on technical standards that give presumption of conformity with specific directives.

[2] 93/465/EEC: Council Decision of 22 july 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives.

spective domestic Member State, but also that these "Notifying Authorities", in the European jargon, have to make sure of the competencies, impartiality, independence, etc., in the long run of the activities of the bodies they had previously appointed. The European Commission quickly stated, at least inside a few sectors, that numerous of the Member States Notifying Authorities were not as vigilant as they should be, and conversely that some Notified Bodies were not as competent or even as serious as they ought to be. This is why the Commission pushed, sector by sector, Notified Bodies and Notifying Authorities to join inside working groups so to share information and favor best practices with regards of conformity assessment procedures. Stating on another hand that Notifying Authorities were not enough involved in the survey of "their" respective Notified Bodies, the Commission pushed progressively forwards another proposal: if Notifying Authorities are not interested in the above issues, European Member States should delegate these tasks to specific independent Accreditation Bodies. Although this proposal has been pushed forwards since decades, and although the European Commission could not legally force Member States to create Accreditation Bodies, the process is now about to be achieved all over Europe. An important step has been cleared (2008[3]) when the European Institutions decided that, on the opposite of what was organized at the Notified Bodies' level, accreditation procedures should not give way to new accreditation markets in Europe. Every Member State should appoint a unique National Accreditation Body, which would be in charge of "its" domestic Notified Bodies accreditation, and Mutual Recognition Procedures between National Accreditation Bodies ensure that Notified Bodies just have to be accredited once so to work everywhere in Europe. As they appear as the "top" of the organizational architecture for insuring the CE mark credibility, National Accreditation Bodies are not expected to compete at the European level; although they get paid by Notified Bodies and more generally by third party certifiers for accreditation services, theses bodies, be they private or public, have to stay non for profit organizations and in principle they work within member state boundaries.

This brief historical account is admittedly selective and leaves out details and also events often presented as historical landmarks such as the Single European Act and the 1992-project. The account instead underlines significant changes in the relation of political regulation and markets in the making of free movement of product. In the early years of the Single Market (1958+) the market was assumed to emerge by itself if only not hindered by a territorial political order; as such the making of free movement of products revolved around *removing* regulation and did not to any significant degree conceive the making of regulation with the making of the common market. From the 1960s *technical barriers to trade* became focus of attention and nuanced notions of regulation as constitutive of markets were developed. The market was no longer expected to emerge by itself; it was to be constructed by regulation – which often proved cumbersome. Since the 1980s the *New Approach* has guided a division of work and thus limited the direct role of political regulation in the making of the market, and through the 1990s and 2000s the *Global Approach* has sedimented an order in which markets are used to make markets – as in the cascade of markets for products, standards and certification services – with accreditation as a 'non-market' crown. The case of breast implants and

[3] Regulation (EC) N°765/2008 of the European Parliament and the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) N° 339/93; Decision N° 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/405/EC.

the Medical Devices Directive will serve to provide a better understanding of these orders of markets.

5. Case: Medical Devices

"Medical device" means any instrument or apparatus intended by its manufacturer to be used specifically for diagnostic or therapeutic purposes and which does not achieve its principal intended action in or on the human body by pharmacological means (from Directive 93/42 CE). To put it differently, medical devices are made for helping patients or disabled persons for the diagnosis, treatment, or compensation of their injury, illness or handicap; but they are not pharmaceuticals. There exist a lot of medical devices, from spectacles or white sticks to pacemakers for example.

The huge and expanding Medical Device sector is worth to be studied (and has been much studied by scholars), first because since decades it is regulated differently in Europe and in the United States, and also because both regulatory systems are criticized at the moment, or are under revision.

In Europe, there exists a definitive difference between medical devices and pharmaceuticals regulations. On one hand, pharmaceuticals have always been considered as too risky products so to be regulated by the New Approach. The Commission and the Member States decided to submit pharmaceuticals to Premarket Approvals (PMA) before they would authorize producers to put their products on the European market. In short, PMAs lead to the setting up of a specialized European Medicines Agency (EMA) which works inside a network with national Agencies. The construction of this network, the rise of scientific expertise, for cost/benefit evaluations in the pharmaceutical sector, and the setting of PMAs procedures took years (Hauray, 2006), but the European regulatory process, with regards to pharmaceuticals, is globally stabilized. Medical devices began to be regulated in Europe, by 1990 and 1993, through the New Approach, and still are. This gave rise to series of harmonized standards, and to a population of specific Notified Bodies (around 70 in Europe at the moment).

In the United States, by contrast, pharmaceuticals and medical devices, at least the riskiest of them (implanted prostheses, pacemakers and so on) are regulated through PMA processes led by the US Food and Drug Administration (FDA) Agency.

These differences, and their consequences, between Europe and the US, with regards of the Medical Devices sector Regulation, have been rather well documented, both by industrials, international "independent" observers, and scholars (Altenstatter & Permanand, 2007). Moreover, since the Medical Device Directive has been under revision for years, and because a recent sanitary crisis concerned directly this under revision Directive (the French 2013 PIP Affair upon breast implants[4]), debates are important inside (and outside) Europe, with regards of a waited new Medical Devices European Directive (Altenstetter, 2013; Singh, 2013).

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[4] Bad quality CE marked breast implants, manufactured in France by the Poly Implant Prothese (PIP) society, were found to cause diverse health problems to wearing patients (2013). There are thousands of victims in France, Europe, and in other countries (South America). The PIP Director (and some of his employees) was convinced by French courts to be a crook when hiding the fact he used non authorized but self-made products for the making of the PIP implants. Victims claimed in several trials, among others against the Notified Body which had delivered numerous conformity assessments certificates for PIP implants.

To put it schematically, these debates oppose those who defend the advantages of a centralized regulation (trough PMAs and an Agency), and those who defend the decentralized and actual European approach, with its standards and third party conformity assessments procedures.

Medical devices industrials, be they European or North American, and often international consultants, mainly favor the present European approach: not only is the European New Approach and its standards held to spur innovation, but also it spares time and gives possibilities for patients. International Consultants, such as PricewaterhouseCoopers or The Boston Consulting Group[5] demonstrate that PMA approval take a much longer time than CE marking, because of administrative and cognitive (lack of expertise) reasons inside FDA. The European and decentralized regulation is much faster, they say, so that European patients are able to get the benefit of innovative products much quicker than the American ones.

On the other hand, other actors – surgeons for instance, whose work is to implant prosthesis – are often more critical of the European approach, for safety reasons. Some critiques have been rather hard: because of the above stated differences between the EU and the US systems, US producers now try first their innovative products in Europe, so that European patients are becoming "guinea pigs" of their experiments.[6]

The recent PIP affair gave new interesting arguments to these opponents or at least critiques of the New Approach[7] (van Leeuwen, 2014). One discovered that in this case TÜV Rheinland, the well known German third party certifier, had delivered for years conformity assessments certificates to the French PIP owner and Director, without having tested or even seriously looked at the products, the breast implants themselves[8]. This point revealed how much the "harmonized standards" were loose, resting much more on procedures (such as Quality Management Systems Standards) than on substantive and descriptive standards, so that the conformity assessment process could be conducted only by checking "papers". On another hand, it was discovered that the FDA had refused to approve PIP Breast implants, so that these products could not be sold in the United States (which explains there are no North American victims).

These statements heated the debates between both positions, in the European Medical Devices Directive revision framework. Some stakeholders would ask back for the creation of a specific European Medical Device Agency, with a PMA system, or at least for a strengthening of "essential safety requirements" and harmonized standards in this sector. But industrials

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[5] Respectively "Medical technology. Innovation Scorecard: The race for global leadership", 2011; "Regulation and Access to Innovative Medical technologies. A comparison of the FDA and EU approval processes and their impact on patients and industry", 2012

[6] Owen J;, "Patients' lives put at risk by faulty medical implants. People are "being used as guinea pigs" by an under-regulated industry, researchers warn", *The Independent*, May, 15, 2011, consulted on line March, 02, 2015.

[7] Mc Culloch P., "The EU's system for regulating medical devices. Now is the time for a radical change", *British Medical Journal*, October 24, 2012; "EU proposals on medical device regulation do not go far enough, say experts" , May 7, 2013, http://www.bmj.com/Press-releases/2013/05/07, consulted on line March, 02, 2015.

[8] This point has been specifically stressed at the time of a trial that opposed in France some PIP breast implants distributors, accompanied by around 1500 victims, to the German notified body which had been chosen by the PIP Director, Tribunal de Commerce de Toulon, Société GF ELECTROMEDICS & Société EMI IMPORTACAO E DISTRIBUCAO LTDA & Société J&D MEDICALS et autres intervenants volontaires *contre* TÜV RHEINLAND PRODUCT SAFETY GMBH, Jugement du 14 novembre 2013.

did not change their views[9]. The persistency of these debates, which can be found also between the European Commission and the Parliament, explain the fact that the European Medical Devices Directive still is on revision, at a time when this sector is part of the discussion of the TTIP.

6. Discussion

Following our account the New Approach and Global Approach can be summarized as several intertwined orders, each of which exhibits specific tensions as well as there are tensions between intertwined orders. There are at least four order apparent in the case (A-D): A) One is what we may term the *order of public authority* that in rough points may be summarized as treaty-directive-member state regulation. This order is both well-described and debated in the integration literature. B) A second is what we may term the *order of new approach harmonization*, that runs along the line directive-mandate-harmonized standard. C) The *order of approval*, found in the levels of organizations (private as well as public) that encompass member state authorities-accreditor-certifier-firm. This is not a hierarchical order in the sense that e.g. accreditation bodies can decide how certification bodies should operate. But it is an order of approval, and each level of organizations depends to a certain degree on the approval by an organization of the next higher order: Firm producing and marketing products depend on approval by certifiers and certifiers depend on approval by accreditors. D) Finally there is what we may term an *order of markets*, summarized by the certification market-standards market-product market where a market for products is afforded by a market for technical standards which again is afforded by a market for certification services.

These orders are intimately connected to but not identical. They also bear witness of openness, not to say indeterminacy. Each of them requires openness to leave room for decisions (rather than determination), and they set up criteria in order to create conditions of calculability and yet they do not allow one level to be calculated based on another level. And in case of a product, such as breast implants, several orders of conditions, of markets, of regulation, can often be followed from it. Here common dualisms, such as state/market, politics/market or regulation/market, are not very helpful as the situation is one of entangled orders that bring together public and private, national and transnational, competitive and non-competitive bodies in one ecology. The Medical Devices case can help us understand such ecologies and the tensions or contradictions in and between orders that characterize them. Put differently, the case can give a better understanding of regulation practices and the recourse to markets.

First, in the "PIP affair" framework, the question of unannounced visits (by the Notified Body at the producer's plant) was raised. The 93/42 directive states that "the Notified Body may pay unannounced visits to the manufacturer",[10] but does not say it has to. In the PIP case, TÜV Rheinland, the German Notified Body, never paid any unannounced visit to PIP's plant. French Tribunal de Commerce de Toulon Judges said that "would TÜV had paid only one unannounced visit to PIP's plant, during the several years it was PIP's NB, they would have discovered PIP's owner was crooking them". But TÜV defended itself by saying that it did

[9] EUCOMED, « Towards a regulation that guarantees patient safety, ensures patient access and keeps innovation in Europe", Eucomed's response to the Commission Proposal for the revision of the medical device Directive, January 30, 2013, consulted on line, March 2, 2015.

[10] 93/42 Directive. Annex II : EC declaration of conformity.

not had to do that, according to the Directive; moreover, TÜV claimed that, according to the harmonized standards that was supposed to fulfill the essential safety requirements, it had to warn PIP' owner of its visits. This controversy points to tensions within the order of harmonization: if TÜV is right in its claim, it may point to unsatisfactory concretization in the technical standards of the essential safety requirements of the directive. It is part of the story that certifiers, such as TÜV Rheinland, are known to take part in developing technical standards for types of products they later are to certify. It is in other words a tension of both bringing together and wishing to keep apart technical expertise and political interests. Thus the question of "unannounced visits" is an example of possible contradictions between loosely formulated "essential safety requirements" and harmonized standards that are supposed to fulfill them.

The question of "unannounced visits" also points to tensions between what we have termed the order of approval and the order of markets. How can legislators imagine that a Notified Body will decide to go and inspect the producer it has in charge through an unannounced visit – and ask the producer to pay for it – when this Notified Body knows that other Notified Bodies would not do so, and that, as the certifiers' market is always open, the producer can shift at any moment for the Notified Body he would prefer? The issue can also be put in terms of principal and agent: in an order of approval the certifier would be principal; in an order of markets it is unsurprising to find that the firm is the principal as it buys a service from an agent (the certifier). Such contradictions between who is the principal are likely when orders are brought together as in this case. Anyway, after the PIP affair, the Commission decided that unannounced visits concerning high risk or class 3 Medical Devices would become "recommended" ([11]), which does not really solve the contradiction.

Further tensions come to fore if a closer look is taken at between *ex ante* and *ex post* control, an issue already debated in regards to the Medical Devices sector (Singh, 2013). In the New Approach framework, Notified Bodies are in charge of *ex ante* regulation: as summarized in the order of approval, producers need conformity assessments certificates before CE marking their risky products and let them circulate inside the Single Market. The Commission has always reminded Member States that this was only part of the problem and that each Member State had also to control CE products that were circulating inside its own frontiers. Most of the time, this *ex post* regulation is done in the order of public authority, e.g. by civil servants (custom inspectors, special services against fraud in France for example). The unresolved questions concern the responsibility of the *ex ante* or the other *ex post* regulator – when facing fraudulent or not conformed CE products – and the one of the relationship (sharing of information for instance) and the complementarity between "European" Notified Bodies and national civil servants in charge of post market surveillance.

The issue of *ex post* and *ex ante* control highlights the territorial state central to the order of public authority in contrast to the order of approval, that does not build upon territorial boundaries. The transnational politics that result from this are well-known in the literature. It is worth pointing to that these transitions from market to regulation and the reverse rest mainly on international standards: conformity assessment procedures (product certification), accreditation procedures ("certifiers' certification") and mutual recognition agreements (be-

[11] EC, Press release, Restoring confidence in medical devices. Action Plan after the PIP scandal tightened control in Europe, 20 June 2014.

tween national accreditation bodies) mainly rest on ISO quality management systems audit standards. In this sense the European transnational politics here analyzed is entangled with international levels.

There has in the EU been interesting debates concerning the order of markets. The CE marking procedures gave way in Europe to a very specific institutional architecture, which to a considerable degree has been built around markets. For opening "real" Single Markets for "risky" products, Member States were asked to designate, then survey during their day to day activities the expert bodies they found competent so to deliver conformity assessments certificates to "essential safety requirements". This regulation by Member States was a prerequisite for opening, at the European level, markets for these certification activities. But, as the Commission stated, Member States were not enough involved in those regulation activities, it progressively pushed Member States to delegate them to independent Accreditation Bodies. Although there were discussions on the subject – should an accreditation bodies market be shaped in Europe? – European Institutions chose not to open a new market at this level: each Member States had to appoint a unique National Accreditation Body, which revenues mainly come from their respective "domestic" Notified Bodies or more generally Third Party Certifiers, and these different non-for-profit bodies are not in competition with one another, but rather share Mutual Recognition Agreements so that, at least in Europe, certifiers could claim that "if they are accredited once, they are accredited everywhere".

The Medical Device Directives are not under revision since or because of the PIP affair. The revision process began several years ago, one of the stated main problems being that Notified Bodies practices could be very different from one Body to the other. More, there had been a series of problems with CE marked Medical Devices, and in some cases little (and often Eastern European countries originated) Notified Bodies were found incompetent or unscrupulous.[12] At the moment, and in the Medical Device Directives revision process framework, the European Parliament voted a specific proposal which stipulates that high risk (class 3) Medical Devices should only be controlled by "super Notified Bodies" the list of which should be drawn and published. The idea is that just a few (5 to 10 at the maximum), among the present Medical Device Directive's Notified Bodies population (around 70 at the moment), could deliver conformity assessment certificates for high risk Medical Devices; this decision – which would restrict the certifying market – would presumably allow a better sharing of "good practices", more harmonized procedures, and suppress black sheep. Another current idea that circulates in the Medical Devices Directive revision framework is to create an inspection or at least survey institutions for Notified Bodies at the EU level.[13] In spite of the setting of National Accreditation Bodies, the problem of Notified Bodies' competencies or of the fact they do not all share harmonized practices seams unresolved, at least in the case of the Medical Devices sector.

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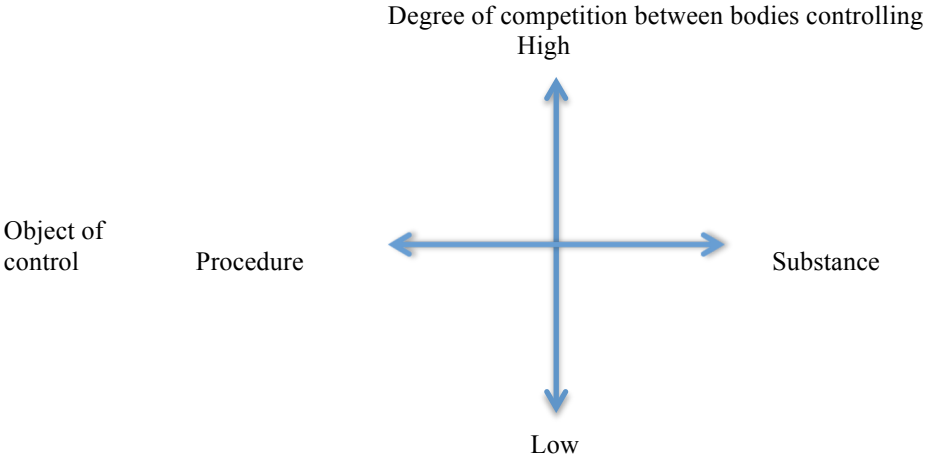
[12] The British Medical Journal and the Daily Telegraph conducted a joint investigation (2012) by submitting an application for a "fake" hip implant: this implant was designed by experts and based on a device that had been recalled from the market because of unacceptable rates of medical problems for implanted patients. Nevertheless, the "fake" medical device was certified and approved by some Notified Bodies (Fry, 2014). For a more general and earlier warning , see Roy (2009)

[13] Informations concerning the ongoing revision process of Medical Devices Directives can be found on the European Commission website: ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/revision/index_en.htm, last consulted, 10/05/2015

One way to summarize these current debates and our analysis is to focus on two central dimensions in the control of products: One is the degree of competition between controlling bodies. Sometimes controlling bodies compete, and may compete more or less, as in the case of certifying bodies we have discussed. At other times controlling bodies are not in competition, such as when a state agency is given a specific authority as part of the public administration. The other dimension is the object of control, and here the distinction is between a control that focuses on substance (e.g. 'does this specific product comply with specific regulations?') on one hand and on the other a control with procedures as when the self-control of firms is controlled (as well-known in management systems and as studied in the literature on 'the audit society').

Figure 1:



In the PIP case the object of control was the self-control of the producer. And the controlling body (the certifier TÜV) was in an environment of relatively high competition. With such distinctions it seems reasonable to recommend that products in high risk sectors (such as implants) are regulated by lower degrees of competition and with more focus on substance than on procedure. This is, however, an issue of further research to discuss and possibly develop such distinctions into a useful tool for policy making. It would of course leave many questions unanswered, some of them only pointed towards in this paper. One is the TTIP and a comparative evaluation of US and EU systems of product regulation (e.g. Schepel). This paper does not provide basis for such an evaluation, but it seems certain that TTIP will add tensions to those already discussed here. Another is the issue of certifier involvement in the making of technical standards and possible entanglement of what is to be controlled and how it is to be controlled. A final issue to point to is the general one of how ecologies of market and regulation can and are shaped and what they do learn us of markets and organization (Simon 1996).

7. Conclusion

This paper has shown that the Single Market builds on intertwined orders, including an order of public authority, an order of new approach harmonization, an order of approval, and an order of markets. The considerable degree of openness and intertwinement resulting from the

simultaneity of these orders also make normal (Perrow 1984) that regulation does not work as intended, sometimes with harmful consequences as in the breast implant case.

At the moment, although many actors recognize that the general architecture which has been laboriously constructed since the first New Approach Directives, with its Notified and Accreditation Bodies, does not exactly work as intended, this construction is not globally criticized, except inside the Medical Devices sector. In this specific sector, on the contrary, both because of old well known problems and of recent spectacular ones, the ones' and the others' positions are very different. To put it schematically, industrials try to maintain this architecture, while bettering it if possible, when others stakeholders are more critique and for some of them, in favour of important changes in the regulation of Medical Devices in Europe. This debate takes place at a very peculiar moment, when Medical Devices is one of the sector which is under negotiation between the EU and the US, in the TTIP framework. In the current Factsheet on Medical Devices [14], the TTIP purpose is to "harmonise the way a medical device is approved in the EU and the US". Although it is stated that both current regulations systems are different, the EU declares that "in TTIP we don't want to harmonise the approaches for the approval of a medical device in the EU and the US", and that TTIP discussions do not have to interfere with the on-going revision of the EU Medical Devices regulations. We may have some doubt about these last assertion: as many critics of the present European Medical Devices regulations often claim that the US ones, with the FDA as a centralized Agency, allows better regulations (Fry, 2014), it will be difficult for TTIP discussions not to interfere with the ongoing revision of the EU Medical Devices regulations.

To put it differently, the TTIP discussions on the Medical Devices sector, and the on-going revision of the European Medical Devices sector regulations are both occasions to the European legislator to reconsider some of the very basics of the New Approach (van Leeuwen, 2014), in the specific Medical Devices sector[15] and also more generally beyond it.

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[14] TTIP, EU negociation texts, chapter by chapter, EU Commission website, February 10, 2015.

[15] The above mentionned European Parliament proposition, of designating just a few "super Notified Bodies" for conformity assessments procedures towards the riskiest Medical Devices, is for instance a way for reconsidering the very basics of the New Approach and its followings

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